

Positives For Positives

A Quarterly Publication to inform the HIV/AIDS Community

**Positive People as part of the Solution,
not the Problem**



**Community Update 2004 from
The 11th Conference on Retroviruses
and Opportunistic Infections
February 8 - 11, 2004
San Francisco, CA, USA**



Positives For Positives

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Community Update 2004 from The 11th CROI

By Jeff Palmer

This year's Conference on Retroviruses and Opportunistic Infections (CROI) took place in San Francisco, CA, USA from February 8 through 11. Nearly 4,000 of the world's leading researchers and clinicians convened at this prestigious meeting. CROI is a scientifically focused gathering with the purpose of providing a platform for translating research into medical practice.

The conference featured the latest research related to HIV and other retroviral diseases. Some of the specific topics covered included virology, immunology, vaccines, therapy, complications of therapy, epidemiology, microbicides, maternal-fetal transmission, pediatric and women's health issues. There were more than 900 peer reviewed abstracts presented, six symposia panels and six plenary lectures. Nearly all of the meeting, abstracts, posters and webcasts, is available at the official conference website, www.retroconference.org.

Production of Community Update 2004 took place during and the day immediately following the meeting. The project was a collaborative effort between IFARA (International Foundation for Alternative Research in AIDS) and Wyoming: Positives For Positives (WPPF). The project was initiated in 2002 by IFARA. Over the next two years, the project evolved into a collaborative effort between the two agencies, IFARA and WPPF.

During the conference, Fred Schaich of IFARA and his production crew, Greg Fowler and Greg Bourdeau set up a small studio in their hotel suite and began four marathon days of production and scheduling. A total of 17 videotaped interviews and two taped segments for later use in a live



Fred Schaich, IFARA, & Greg Fowler at work during production

satellite broadcast were done during this time. The live satellite production took place February 12, the day following the conference. The broadcast was available for live downlink across the U.S. or could be taped for later viewing.

The satellite uplink consisted of three segments. The first focused on antiretroviral therapy. The remaining two segments focused on HIV/HCV Co-Infection and metabolic complications respectively. A limited supply of DVDs and a series of VCR tapes of the satellite uplink and the interviews are available. Further information on availability can be obtained directly from IFARA, 222 SE 30th Pl., Portland, OR 97214, USA; Phone: 503-736-0194; Fax: 503-736-9908, Email: ifara@comcast.net. A complete listing of panel participants and individual interviews can be viewed in the box below.

In addition to the DVDs and VCRs, audio streaming of the interviews is available at www.thebody.com, selected transcripts from the interviews are published in this issue of *Positives For Positives* beginning on page four (4) and all transcripts will be available for viewing or downloading at the WPPF website, www.pos4pos.org

Panel Participants

Stephen Becker, M.D., Pacific Horizons Medical Group, San Francisco; **Lisa Capaldini, M.D.**, California Pacific Medical Center, San Francisco; **Andrew Carr, M.D.**, St. Vincent's Hospital, Sydney, Australia; **Martin Delaney**, Founding Director, Project Inform, San Francisco; **David Evans**, Moderator, Project Inform, San Francisco; **Doug Dietrich, M.D.**, Mt. Sinai Medical Center, New York City; **Daniel Kuritzkes, M.D.**, Partners AIDS Research, Cambridge, MA; **Daniel Raymond**, Harm Reduction Coalition, New York City; **Fred Schaich**, IFARA, Portland, OR; **Kenneth Sherman, M.D.**, Univ. of Cincinnati, College of Medicine, Cincinnati, OH

Interviews

David Back, Ph.D., PK Research, Ltd., London; **Calvin Cohen, M.D., MSc**, Commun. Research Initiative on AIDS, Boston, MA; **Huntly Collins**, AIDS Vaccine Advocacy Coalition, New York City; **Alex Coutinho, M.D.**, The AIDS Support Group, Kampala, Uganda; **Miguel Cashat Cruz, M.D.**, Hospital Infantil de Mexico, Mexico City; **Eric Daar, M.D.**, Harbor-UCLA Medical Center, Torrance, CA; **Kevin De Cock, M.D.**, CDC, Nairobi, Kenya; **Richard Elion, M.D.**, George Washington University, Washington, DC; **Joel Gallant, M.D.**, Johns Hopkins University, Baltimore, MD; **Peggy Johnston, Ph.D.**, NIAID, Bethesda, MD; **Joep Lange, M.D.**, University of Amsterdam, Amsterdam, The Netherlands; **Ambassador Stephen Lewis**, United Nations Special Envoy on HIV/AIDS in Africa; **Franco Lori, M.D.**, Research Institute for Genetic & Human Therapy, Washington, DC; **Simon Mallal, M.D.**, Royal Perth Hospital, Perth, Australia; **Lillian Mworeko**, National Forum of PLHA Networks, Kampala, Uganda; **Sharon Nachman, M.D.**, Stony Brook Health Sciences Center, Stony Brook, NY; **Charles Rice, Ph.D.**, Rockefeller University, New York City; **Robin Shattock, M.D.**, St. George's Hospital Medical School, London; **Octavio Vallejo, M.D.**, Pacific AIDS Education Training Center, Los Angeles, CA

Interview with
Ambassador Stephen H. Lewis
United Nations Special Envoy on HIV/AIDS in Africa

P4P: We're speaking with Ambassador Stephen Lewis, the U.N. Special Envoy on HIV and AIDS in Africa. Ambassador Lewis, I attended your presentation yesterday and you had six rather profound areas that you thought were really critical in terms of addressing the HIV pandemic. I would like to run through those one at a time here. The first one you talked about was the money that's needed. Please tell us more about that.

AMB Lewis: Around financing and resources, UNAIDS, which is the UN body that does most of the statistical work, has indicated that we'll need \$10.5 billion to address all of the aspects of battling the pandemic internationally by the year 2005, and we'll need \$15.5 billion by the year 2007. Last year, we had about half of what we'll need, a third of what we'll need come 2007. Where the additional money is coming from is not yet clear even with the initiative of the President of the United States. So there is a tremendous shortfall at this moment in time of several billion dollars, which reflects itself in the work of the Global Fund on AIDS, Tuberculosis, and Malaria, which is the central financial institution to do the most intelligent coordinating throughout the world. So the basic and profoundly anxious truth is that the donor countries, the wealthy G7, the big Western countries, have simply been utterly delinquent, criminally negligent over the years in refusing to supply the developing world with the dollars that are needed. That pattern is improving, it's not as bad as it was, but we're nowhere near what we need.

P4P: Some of the other things that you talked about, generic drug combinations... I'm guessing there was a specific generic combination that you had in mind...

AMB Lewis: I raised the generic combination in the context of the World Health Organization's (WHO) new credo, new determination, to put 3 million people into treatment by the year 2005. One of the things that should make that possible is a fixed drug combination, a triple-therapy, which is available from generic drug manufacturers, not available from brand name pharmaceuticals. But available from generic drug manufacturers, which requires only 2 pills a day, morning and evening, and that seemed to everyone to be the best possible combination. I'm not familiar with the precise drug combinations, but it is the only triple-therapy combination of its kind, based on 1 pill in the morning and 1 pill in the evening, and its cost is significantly below anything else on the market. So it seemed to me that that drug, which is being

used in the clinics that do prevention of mother-to-child transmission and then treat the mother and the family, that is being used by big NGOs who have treatment capacity on the ground, like Medecins Sans Frontieres (Doctor's Without Borders), and which is being used in some countries by governments that are starting to do treatment, that that is the way it should be done. It has been pre-qualified and approved by the WHO, the pre-eminent body to approve drugs internationally. The worry is that some countries, possibly like the United States, may decide to pay more to buy the drugs independently and individually from the major pharmaceuticals, and that would be a pity. Not because the drugs aren't of good quality, but because the regimens are more complicated on the one hand, and the cost is greater on the other.

P4P: In your presentation yesterday you stressed community involvement. Talk a little bit about that. What kinds of community involvement versus government involvement?

AMB Lewis: That's actually a good distinction between community and government, because a government tends to be more dogmatic, more authoritarian, more prescriptive, not very collegial, so we've learned over time. I don't know why that should be, but that tends to be the way it works. You can't do the treatment unless it's at community level. We're not going to have an apparatus of high-flying doctors and high-flying bureaucrats



to make it real, particularly in the rural areas. You've got to get it down to the community. When I talk about community what I really mean personally, and I think a lot of people share this, is the involvement of groups of people living with AIDS. The most lamentable part of the organization of the battle against AIDS on the ground is the way in which people living with AIDS are excluded. And the way in which their voices are not taken seriously. And the way in which they are not invited to take part in decisions. But people living with AIDS know more about the reality of the problem than anybody. They are the experts. So if you involve the community, meaning fundamentally the groups of people living with AIDS in communities at the grassroots, along with the other parts of community organization of course - the municipal structures, the local community activists, the schools, the health district - but the people living with AIDS are absolutely the key. And if you get them involved with the local medical facility in a kind of

partnership, when they're working at distributing or dispensing antiretrovirals, you'll always have a better program. And that's one of the toughest battles, because people living with AIDS are uniformly excluded in country after country as the government engages in a kind of stigma, while pretending that it cares about discrimination.

P4P: Going a little bit further with community...There certainly needs to be some capacity building in community, because you're bringing together two very divergent groups, in terms of backgrounds and education. How does that play into capacity building for community? Where do you see that?

AMB Lewis: Well it's just extremely difficult, because of course what has to be realized is when you're talking about a continent like Africa a lot of people have died, and a lot of people are very ill. So a lot of capacity has been lost. Lost forever. It's going to take time to rebuild that capacity. You frequently have to rely on the people who are treated. That's the wonderful thing, as you get treatment in place, people regain their strength and their involvement, and they return to work and you have a much larger group to call upon. But you'll have to do the training, and the training will come from outside organizations who give some help; it will come from community health workers, counselors who are associated with a hospital or with a district health clinic. The training will start at the top with doctors and nurses and pharmacists, and gradually it will move out to counselors and community health workers, and get down to the community. Countries have to very carefully sort out how they fill these gaps, how they get people trained in the community, because so much of the capacity is lost. It's heartbreaking to visit some of these communities and realize how many of the key community activists have died.

P4P: One of the things that really struck me yesterday was your emphasis on opening the doors to women and the impact of this disease on women. It seems that too often women are the forgotten part of this epidemic, and I was really pleased to hear you speak so clearly on this. Could you talk about what it means to open those doors?

AMB Lewis: The area that I feel most strongly about in terms of the entire pandemic is the ferocious assault on women. Women are more vulnerable; they are disproportionately affected and infected in huge numbers. Of the 25 to 30 million people living with the virus between the ages of 15 and 49 in sub-Saharan Africa, 58 percent are women; and in the younger age groups, which are crucial, 60 to 70 percent are women and girls. They are tremendously vulnerable to predatory male sexual behaviour. All of the laws, all of the realities discriminate against women. They lose their property rights, they lose their inheritance rights. There's a tremendous amount of sexual violence, which transmits the virus. There is an absence of gender equality so palpable, so frontal, that women are struggling with enormous difficulty in the face of the pandemic. And what is even more important,

of course, is that the men tend to get infected first, often in the urban centers, they come home, they pass the virus to their wife or to their partner, and the partner gets ill. While she's ill, she not only looks after herself, but she looks after others who are ill in the community, she looks after the orphans, she does the farming. Women carry the entire burden of care and sustaining the entire society. Therefore, when one is dealing with the pandemic, one must do things that empower women; one must make sure that women have particular access to medication and to care. And in fact we have to stop the endless nonsensical run of meetings and reports, and just zero in on the inappropriate male behaviour and put them in jail for long periods when they engage in rape and sexual violence, and change the laws that give them the free run of the land. There just has to be very firm dealing with the men who are making such a dreadful hash of gender equality.

P4P: I'm so happy to hear you say those things... Last item, and it certainly plays into the impact on women, as well as the impact on orphans. When you have a child who has no parents, no schooling, no job, no hope, how do you see that playing into the potential for terrorist recruitment? What about the terrorist who comes to a young person in this situation and says, "Here's 15 pounds of...; strap this on yourself and walk into an embassy."

AMB Lewis: That's a particularly American fear. There has been some real discussion about the question of security in these countries. I think it's probably fair to say - I want to phrase this carefully - that if you have large numbers of orphans who are rootless and homeless and foodless, and bewildered by their position, and feeling pretty angry and anti-social about what has happened to them, they are a lot of gangs in many of the urban centers in some of the African countries - Nairobi, Johannesburg, Lagos - you have a possibility of real instability. I won't go further than that. Poverty can be the basis for the attraction of extremist groups, as much as disease can be, and poverty and disease are inevitably linked. But what HIV/AIDS has done is introduced the possibility of instability down the road, because these young kids who, as you say, have had no nurturing, no love, no affection may become ominous if they are angry and in gangs and distressed. So, there's a possibility of instability and the important thing, therefore, is to start moving now to do the best we possibly can to respond to the orphan crisis, which is in the millions. We expect there will be over 20 million orphans under the age of 15 by the year 2010; roaming the landscape of Africa, looked after by grandmothers, living in child-headed households, desperately absorbed by communities that are already impoverished, unable to go to school because they can't afford the school fees. The world really needs to concentrate on what's happening to these orphan children who have inherited a sad finale to a process they had no part in. And that's the toughest challenge of all.

P4P: Ambassador Lewis, thank you so much for your time.

Interview with
Robin Shattock, M.D.
St. George's Hospital Medical School, London, UK

P4P: We're pleased to have as our guest Dr. Robin Shattock of Saint George's Hospital Medical School in London, England. Dr. Shattock presented yesterday on microbicides. Doctor Shattock, I know that there have been some gains in knowledge that have led to new approaches in tackling the problem of development of microbicides. What are some of those new developments, and what barriers still remain?

Dr. Shattock: Well, it's an exciting time for microbicide development, partly because the field is being taken more seriously, and that's due, in part, to the fact that at the moment there isn't an effective vaccine that's likely to be rolled out in a global way in the near future. Microbicides have the advantage that they may well be able to be developed quicker and faster than an effective vaccine. Ideally, at the moment, they're being targeted to be developed for the developing world, so that they can give women a means of protection that they can choose and control themselves, so that where there is inconsistent or no condom use they still have other options. One of the significant things is we know that a major risk factor for women is to actually be in a stable monogamous relationship, and in those relationships condoms are used far less, partly because fertility is very important in many parts of the world. But it is in those relationships often where HIV transmission appears to occur. This is a critical concept that could have big impacts in terms of prevention therapy or prevention treatment.

P4P: In terms of the "A-B-C", it kind of like puts a dampening effect on the "B" part of that term - being faithful?

Dr. Shattock: Yes. Absolutely. So if you're in a monogamous relationship you may be faithful, you're certainly not going to want to abstain if it's a relationship. But being faithful doesn't necessarily protect you.

P4P: And in many parts of the world that's placing women at higher risk.

Dr. Shattock: Absolutely.

P4P: In terms of where the development of microbicides is at this point, could you discuss some of the mechanisms that we are exploring now, especially as they relate to preventing entry?

Dr. Shattock: What we would call first-generation microbicides, the things that have been worked on for the longest and are about to enter Phase 3 clinical trials, the majority of those work on a charge basis, so they would be called polyanionic molecules. On a cell sheet they're very long chain molecules that have a high level of negative

charge, and these compounds work by blocking HIV fusion with susceptible target cells. They work in a very nonspecific fashion, so they're likely to be active against a wide range of viral types. Unlike, for example, antibody approaches, mutation of the virus is less likely to be a problem for such an approach. They're ideal because they're very cheap to manufacture and cheap to distribute. But what have no proof of concept at the moment, as to whether they'll work, so we need to try these in a Phase 3 trial to see if they are efficacious.

Alongside those, there is still one compound that's been taken to Phase 3 trial that destroys the virus by lysing¹ its envelope. This is a relatively new molecule and has a much higher selective index, so it's much more selective about the lysing virus particles and epithelial² cells than the nonoxynol-9. Hopefully it has a better safety profile, and again, we need to try it in a clinical trial to see whether it works or not.

And then there's one other approach, which is using a pullout called "buffer gel", that simply maintains a very low pH³ in the vaginal lumen⁴ - that's a pH of about 4.5 - that in itself can inactivate viral particles.

So those are the first-generation things are going to clinical trials this year. But then, following them up very quickly are alternative approaches. A lot of drugs that have been used in therapeutics are now crossing over and being considered as microbicides. Certainly some of the antiretroviral compounds, particularly tenofovir (viread) has been formulated as a

gel as a vaginal microbicide, and also some of the newer NNRTIs are being considered as microbicides. Those are compounds that have a good chance of working, but one of the issues with those will be their impact on other therapeutic use of antiretrovirals, and that's still an unknown in terms of resistance issues.

P4P: Are we looking at a certain percentage of efficacy? And, can you estimate a timeline when we might be able to obtain a microbicide that achieves that percentage of efficacy?

Dr. Shattock: At the moment what we would like to achieve with a first-generation product would be something that shows 60 percent efficacy. That will be complex, because proving that in a clinical trial setting will require good compliance by the subjects, so something might be much more effective than 60 percent if it's used consistently. But in a trial setting I think that 60 percent is probably a good goal to go for. We also know from some of the modeling that a product that has 60 percent efficacy, if it were actually distributed through distribution channels that already exist to



20 percent of people who would use that product, within a 3-year time period it could have actually prevented 2 and a half million infections, which is quite an achievement.

In terms of timelines, if the first-generation compounds show efficacy in a clinical trial they could be rolled out into the marketplace by 2010. But we have no proof of concept of a microbicide against HIV, so it's much harder to know whether we'll be successful. I think what the microbicide community needs to gear up to do is to make sure that we can try as many different types of products to give us the highest chance of success. One of the problems is that a Phase 3 clinical trial is extremely expensive. It would cost in the region of \$30 to \$40 million dollars, and would enroll anywhere between 3,000 and 7,000 women. So there's only a certain capacity for doing clinical trials, and clearly to date there isn't enough funding to support all the clinical trials we'd like to do. The perhaps more pessimistic viewpoint would be that it would need several rounds of Phase 3 clinical trials, which would mean that it could be delayed up until 2016. The difference between an approach where you try as many different things early on, and perhaps get an achievable target of 2010, and a pessimistic viewpoint that would say 2016, would be, in practical terms, a difference of preventing 5 million infections.

P4P: Would you say the take home message from that is, people need to be speaking to their legislators and governments about adequate appropriations for this type of research?

Dr. Shattock: Absolutely. Clearly everybody wants more funding, but the relative amount of funding that goes into microbicides research versus vaccine research is very small. Although we're talking perhaps hundreds of millions of dollars, we're not talking billions of dollars. And it is - with enough funding, enough political will, enough cooperation between different funding agencies and governmental agencies - certainly an achievable goal.

P4P: When we're talking about polyanionic molecules, those could have an effect on other sexually transmitted diseases as well?

Dr. Shattock: Yes. Certainly they seem to be quite effective against herpes simplex, and they may be effective against other STDs as well. There are some differences between some of the different candidates. But an impact on other STDs is good news in terms of human health, but also may have an impact on HIV transmission itself, because there's such a close association between other STDs and HIV transmission.

The other, I think, important concept is that, although these have been pushed very much as allowing women to be able to make their own choices in terms of protection, they're also likely to prevent transmission from women to men. Especially in a developing world situation where we know that lots of women are unaware of whether they are HIV positive or not, if an HIV positive woman is applying a product that may actually prevent her transmitting the virus to her male partner. This is an important concept, because, again, if men think it will be protecting them, they're more

willing to encourage their female partners to start using these products.

P4P: That's an interesting point. In closing, aside from money, what are the major hurdles that you see in the development of vaccines?

Dr. Shattock: One of the major hurdles is the regulatory pathway. Clearly nobody wants to take something into the developing world that will be dangerous. But it's very hard to do a clinical trial along FDA standards, and most of the developing world looks to the FDA to set those standards. There is an ongoing conversation between those people who are planning these Phase 3 trials and the FDA, and I think it needs to continue to be an ongoing dialog, because with a new type of drug what the FDA would usually expect is that it would be administered as a prescription-only drug for up to 10 years. Now clearly a product like this is only going to work if it can be sold on every street corner and is readily available. That's going to be a major hurdle that needs to be talked through with the regulatory bodies, both in the U.S., in Europe, but also in the countries where these products are going to be used.

P4P: The FDA regulates in the United States. In Great Britain you have an equivalent to the FDA...

Dr. Shattock: Yes.

P4P: ... and the situation is pretty much the same for the EU community as well.

Dr. Shattock: It's similar. There are some subtle differences, and it may be that an approach through the European regulatory bodies may be a way to go. But also the other factor is that some of these products are being funded or developed by small biotech companies, and although they are willing to provide these for use in the developing world, they would still like to get drug registration in the developed world. So they are also keen that it goes down an FDA route.

P4P: Doctor Shattock, I want to thank you so much for the time that you've taken here with us, and certainly on behalf of all those people who could not be here.

Dr. Shattock: Thank you.

1 Lysing; from lysis: 2 : a process of disintegration or dissolution (as of cells). Merriam-Webster Dictionary.

2 Epithelial, from epithelium: 1 : a membranous cellular tissue that covers a free surface or lines a tube or cavity of an animal body and serves especially to enclose and protect the other parts of the body, to produce secretions and excretions, and to function in assimilation. Merriam-Webster Dictionary.

3 pH: a measure of acidity and alkalinity of a solution that is a number on a scale on which a value of 7 represents neutrality and lower numbers indicate increasing acidity and higher numbers increasing alkalinity and on which each unit of change represents a tenfold change in acidity or alkalinity and that is the negative logarithm of the effective hydrogen-ion concentration or hydrogen-ion activity in gram equivalents per liter of the solution; also : the condition represented by a pH number. Merriam-Webster Dictionary.

4 Lumen: 1 : the cavity of a tubular organ <the lumen of a blood vessel> Merriam-Webster Dictionary.

Interview with
Kevin De Cock, M.D.

U.S. Centers for Disease Control, Nairobi, Kenya

IFARA: We're here today with Dr. Kevin DeCock, who is Director of the CDC, Kenya. This is the third year you've been kind enough to grant us an interview. Thank you. Before we get too far along, I believe that you had a large part to play in the 11th Conference on Retroviruses and Opportunistic Infections, where we are today. Perhaps you can start us off there?

Dr. DeCock: Yes, thank you. This conference over the past few years has shown increasing interest and attention to the global aspects of the epidemic, which is very important. There was a workshop on Sunday morning, just before the main conference opened, for young investigators where members of the program committee presented some data, and I gave a 15-minute talk on the global epidemiology. We'd just heard from Dr. Jaffe from [the U.S.] CDC about the situation in the United States. The U.S., of course, remains the most heavily affected country in the industrialized world. I gave an overview of the rest of the world. The trends in Western Europe have been very much the same as you've seen in the United States with the dramatic impact on the reduction in new AIDS cases from the use of highly active antiretroviral therapy (HAART), a continuing epidemic of new HIV infections, particularly among men who have sex with men. But an interesting difference that we see in Western Europe that we don't see in the U.S. is the importance of imported infections from Africa - African people who have migrated to Western Europe and are showing up with diagnoses of HIV and AIDS, and make up a substantial proportion of the heterosexual cases.

The other very important trend in Europe has been seen in Eastern Europe where there has been a very important, rather dramatic epidemic of HIV infection, in the former Soviet Union particularly, largely related to injection drug use. This is a very high incidence of new infections, and this will be a very important area to watch. Interventions for injecting drug users and their sex partners, prevention interventions, are really extremely important.

The situation in Asia is fairly stable. Some countries have had a very successful experience, particularly Thailand. Thailand has done a very good job of controlling the sexual transmission of HIV, reducing it. In that country it was largely related to commercial sex, and by instituting a successful condom utilization program in the context of commercial sex, as well as to reduce the utilization of commercial sex, there has been a very rewarding decline in the heterosexual transmission of HIV in Thailand. They've also instituted a

quite successful mother-to-child transmission prevention program. Where they have not done so well is in the problem of injecting drug use. About 40 percent or more of injecting drug users in Bangkok, for example, are HIV infected and that's a much more difficult problem to deal with.

The future of the Asian epidemic, I think, will be largely determined by what happens in India and in China. These two countries have such huge populations that even a low prevalence of infection in those countries constitutes a very large number of people. The future of the epidemic will depend heavily on events in those two settings.

But all of that is fairly modest compared to what we continue to see in Africa. Africa continues to represent over two-thirds of the world's HIV infected people of the new HIV infections that occur annually, and of the HIV deaths. The latest report that was published at the end of last year, 2003, from UNAIDS and WHO, estimated there were about 40 million people in the world infected with HIV. About 28 million of those are Africans. Of the 3 to 3.5 million deaths

that have occurred, again over two-thirds are in Africans; and of the 5 million new infections, close to 70 percent are in Africans. So, this very poor continent continues to bear the brunt of the disease.

In my talk I gave an overview of the data, but I emphasized some of the impact that we see in Africa. Firstly in parallel with the AIDS epidemic, there's a major escalation of tuberculosis, and we

continue to see that in virtually all countries, uncontrolled. Secondly, the social demographic, economic, and family impact is, of course, enormous. The third major impact that I briefly mentioned was that of orphanhood. It's estimated that there are over 10 million children in Africa who have lost one or both parents to AIDS, and this is a problem that has widespread implications, including security implications because these children grow up with very few prospects, a very bleak future. When you see the swollen numbers of children on the streets, for example, many African cities to some extent - to a large extent - this is due to the AIDS epidemic. And finally, fourthly, one of the things that I think also is attracting more attention is the relationship between the HIV/AIDS epidemic in Africa and the question of food security. The interaction between HIV increasing mortality and so on, and the poor state of agriculture in the declining returns of agricultural work, is a complex interaction, but is receiving more attention. In a nutshell, that's what I talked about at my session.



In this country, when we are trying to obtain new funding, we go to the Congress and we testify, we send letters with arguments based both in fiscal and moral responsibility, and sometimes global activists come to the U.S. to testify about the need and ask directly for help. As you've said over the years, there are infrastructure needs, and now we're seeing programs delivering actual treatments, and it seems to be an advance.

Dr. DeCock: Yes, I think we have to be careful not to paint everything as a totally hopeless picture and an empty glass. Over the years there has been progress in every sphere. We've seen real examples of leadership resulting in increased resources. Compared to last year the resources that will be available this year are substantially increased, and I think we also need to focus on how those resources are used at the country-level. We need to keep asking, Are we doing enough in the industrialized world for this problem? But we also need to ask, Is Africa doing enough in terms of leadership, in terms of responsible use of the available resources, in terms of doing what doesn't take any resources sometimes, and using money responsibly? Everybody has their part to play.

IFARA: You talk about leadership and we have certainly seen it at the conference. Over the years we've had Bill Gates, Jimmy Carter, and Bill Clinton who have done good things for AIDS, and now in this other panel there are some clear leaders there. Maybe you can talk about that. Maybe you'd like to start with David Miller?

Dr. DeCock: Yes. Before the conference formally opened, there was an international symposium. We had four speakers. The first was from the World Health Organization (WHO) in Geneva. The WHO has launched an important initiative, the so-called "3 By 5 Initiative", which aims to get 3 million people onto antiretroviral therapy by 2005. That is really working in parallel with the PEPFAR, the President's Emergency Plan For AIDS Relief, the U.S. government effort to increase access to therapy, which is aiming to provide care in the general sense of the word, including for orphans, to 10 million to prevent 7 million new infections by 2008, and to have 2 million people on therapy. We're seeing international movement for sure. David Miller from the WHO talked about a very important issue, which is that of HIV testing. I think there's increasing realization that we have not used HIV testing adequately as a prevention tool and as a tool for entry into care, and if we're going to meet the targets of 3 By 5 or the PEPFAR targets of 2 million on therapy by 2008, we have to test many tens of millions of people, because we can't provide care if we don't know who's infected. It's estimated that in Africa probably less than 10 percent of people who are infected know their serostatus. This raises huge questions about our approaches to the use of the HIV test: how do we make it much more routine and demystify it? It raises very practical logistics questions as well. How do you develop the infrastructure to do all this testing? Can we produce enough rapid tests to meet the demand? And so on. That was the subject of David Miller's talk, a very timely and essential topic.

We then heard two presentations from sub-Saharan Africa that were encouraging and inspiring in their own way, rather different but both illustrative of the kinds of multidisciplinary responses needed. The first was from Dr. Gavin Churchyard, who works for the Anglo-American Gold Mining Company. The gold mines in South Africa are an interesting and challenging work environment. They've traditionally over the years had very high rates of tuberculosis, because South Africa has high rates but also because there's a particular lung disease related to gold mining, an industrial lung disease called silicosis, which predisposes people to tuberculosis. They've then had a rapidly escalating HIV epidemic related to sexual behavior, heavy use of commercial sex, and so on. Again, in the context of everything we know about the gold mines and South African history, the single-sex hostels that men live in and so on, really it's a very conducive environment to generating a rapid HIV epidemic and associated TB epidemic. [Dr. Churchyard] talked about what the company is doing to provide HIV/AIDS prevention and care, and they've mounted an apparently very successful program. It's in its early stages, but they have many hundreds of people on therapy with very promising results, such as a dramatic decline in mortality in men accessing care. It's a very good example of leadership; a well thought out program ethically conducted, really quite impressive, and a role model for other multinational businesses and local businesses as well. Working with the private sector is immensely important.

At the other end of the spectrum, Dr. Alex Coutinho from The AIDS Support Organization, TASO, in Uganda, talked about how to deliver care to people living in poor rural areas. He opened his talk with a picture of a mango tree, with some people underneath it, and said, "This is the clinical situation in which we have to deliver care. Deliver it under the mango tree." TASO has existed for a long time now. It's one of the first NGOs for AIDS set up in Africa. It's a wonderful organization, and they have developed a most impressive comprehensive HIV care program. Dr. Coutinho talked about his experiences related to that. Just like in South Africa in the gold mines, if people are sick and they get triple-therapy, they do well if they take their drugs. That's true in South Africa, it's true in rural Uganda, it's true in New York City.

The final talk in this introductory session was from Thailand, giving an overview of Thailand's quite successful prevention program and their efforts at delivering mother-to-child prevention services using antiretroviral drugs, as well as care. It was a useful session and very encouraging, I think, because literally two or three years ago, certainly not in 2000, I don't think we could have imagined seeing real programs developing, delivering real care interventions including antiretroviral drugs at an affordable price.

IFARA: Are there any other challenges that you feel are worth mentioning at this point?

Dr. DeCock: I think there are. There are a couple that I spend my time pondering about. Firstly I'm glad that you didn't ask me about what I said last year, because I think I'd have a

challenge remembering what I said last year or the year before. (Laughter.) There are some constant themes that I do think about.

The first one, very basically, is, Are we taking this problem seriously enough in relation to what it represents? There is no greater problem facing the African continent, and I still think that the situation in Africa is radically different from elsewhere in the world. We won't go into why that is, but there is nowhere else in the world where you find rates of infection as high in as many places as you do in Africa. And we have to ask, Is Africa itself responding to this with the necessary vigor and is the rest of the world supportive enough? I think the answer is no, that it's not. There is no greater problem. We read in the newspapers of all the terrible things that go on, the wars, the conflicts, the crises that governments deal with, and yet none of them have the implications of the AIDS epidemic. It's the greatest crisis the continent has faced since slavery, since the slave trade. It has the same implications. So that's one general theme.

The second one, I think, is more difficult. In terms of our policies and our interventions, are we being vigorous enough? An example of what I mean is the new attitudes we need toward HIV testing, to make it much more routine if we're going to deliver prevention and care interventions. I often challenge people with the question, "If we had a prevalence in the United States of 25 percent, what would our prevention and care programs look like? What would we do? What would we do for children, for adolescents? What would we do about HIV testing? Would it be completely voluntary with pre-test counseling? Would we make it more routine? Would we be much more exacting about it, as we have been in the past for other diseases?" " I compare it to how we responded to the SARS epidemic, compared to what we're doing for AIDS in Africa. I think there's some deep thinking to be done, especially now that there's hope for therapy and there's more resources. I think there is some deep thinking to be done about what else we should be doing. I think there are a lot of difficult questions that we haven't adequately faced and the reason has always been, Well, we focus only on prevention in Africa and there's nothing one can do when you find people are HIV infected. That's always been a sort of let-out clause. I think we seriously need to ask, in a high-prevalence setting should our prevention and care programs be based on universal knowledge of serostatus, should every citizen know their HIV status? Ideally on a voluntary basis, of course. If we had such a situation in the United States I think that's probably what our programs would be based around.

IFARA: So you would think that maybe we wouldn't look at reporting, or is that something we would continue to work on - required reporting?

Dr. DeCock: Well, reporting is important as a surveillance activity. The reason we do HIV and AIDS reporting is that we track the epidemic using that information, and that's a core of public health responsibility, so we know where prevention and care services are needed, where to target the interventions. So that's a quite separate issue.

IFARA: When you have a stigma so heavily attached to AIDS...

Dr. DeCock: You're right to raise the issue of stigma. Stigma remains a big problem in Africa. A very, very big problem. On the other hand, how do we deal with it? I've come to believe that stigma needs to be dealt with face on. That if we keep treating AIDS as different, then indeed it will be viewed as different and will be stigmatized. Everybody needs to work together to make it more normal, to take the stigma away. One of the ways of doing that is for more people to know their serostatus and share their status. That's where we need leadership from African leaders themselves, from prominent members of society. Someone to say, I live with HIV.

IFARA: I really appreciate your efforts and your presence here today and the interview. I'm hoping that we can have you back again.

Dr. DeCock: It's a pleasure. Thank you for inviting me.

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Interview with
Franco Lori, M.D.
Research Institute for Genetic and Human Therapy (RIGHT)
Washington, DC and Pavia, Italy

IP4P: We're here with Dr. Franco Lori of the Research Institute for Genetic and Human Therapy (RIGHT) based in Washington, DC and Pavi, Italy. Dr. Lori has been doing a lot of work in immune-based therapies and immune-modulating drugs. Dr. Lori, perhaps we could start with immune-based therapies, and you could describe some of the things you're working on at the Institute.

Dr. Lori: Yes, the concept we are working on is to use drugs that act on the immune system that could become useful component adjuncts and synergize with existing antiretrovirals. There are many ways to work with and around the immune system. The one we chose is to work with drugs that have anti-inflammatory properties, because I think there is enough evidence out there that over-activation of the immune system is probably the leading pathogenetic cause of HIV/AIDS and of the progression of the disease, so that if we could decrease the amount of over-activation and "cool down" the immune system, which is really too hot and heated up, then we could benefit from that intervention in terms of better durability of antiretroviral therapy, better survival, and better quality of life for the patients. We are trying to go in a somewhat different direction than people dealing with antiretrovirals usually do, but we think it's a good compliment to the existing therapies.

P4P: I know in your immune-modulating drugs, certainly HU1 has been around for a long time, but I also understand that you're doing some work with, microphenolic acid... am I saying that correctly?

Dr. Lori: That's right.

P4P: Could you describe some of that work?

Dr. Lori: The news with hydroxyurea is that we finally completed our 702 study. It was a large study on different doses and schedules of the drug. To our surprise we found out that the lowest dose, which is 600 mg once a day or 300 mg two times a day, almost half of what we were used to employing in HIV therapy, is not only less toxic as one would imagine, but it is by all parameters we measured more effective. It has a high degree of increase of CD4 count, and the antiviral efficacy is far superior and statistically significant. So, I think we have to revisit the concept of the use of hydroxyurea with a dosage that is much lower than the one we were using, which frankly was becoming too toxic especially when we were moving towards 1200 mg. That was way too much. That was the wrong direction to take. So I think we have to revisit the concept of the use of hydroxyurea

at low dosage, because it's less toxic and much more effective.

Now microphenolic acid is another drug, and please keep in mind that when we talk about cytostatic drugs, although they more or less act with similar mechanisms, they are all different, one from the other one, like antiretrovirals. So microphenolic acid has slightly different characteristics. It's more often immune-suppressant, whereas hydroxyurea is a cytostatic drug. The cytostatic drug really stops cell division or reduces cell division, so that there are less CD4 lymphocytes ready to be infected by HIV, there is less immune activation. Microphenolic is more often immune-suppressant and has been used in the past as such. We have to figure out exactly what the difference is between all these drugs and choose the best candidates based on their properties.

P4P: Do you think there's a possibility of using hydroxyurea and microphenolic acid in combinations?



Dr. Lori: That's an interesting question. I've always been reluctant to consider a combination of immune-modulating drugs before understanding the mechanisms, but I know that people in France, for example, have combined hydroxyurea and IL-2, which is something I would never have done myself, but they have very good results. So, yes, it is a possibility. But I would like to

understand first how it works, and second the dosage. I think the 702 study fixing the optimal does of hydroxyurea has been very important for us, because we can do damage by using the drugs in the wrong concentration. We learn a lot when we dose and schedule properly those drugs, and...microphenolic is going to require some work before we understand what the best dosage of the drug is.

P4P: Is microphenolic...is that...where is that at in terms of the approval process at this point? Are we talking in vitro at this point, Phase I I&D application, where are we at in terms of moving that along into clinical practice?

Dr. Lori: We have to appreciate that both hydroxyurea and microphenolic are drugs that are approved for other diseases, so they are out there, they are on the shelf. But you cannot use them for HIV except for compassionate use or in the context of clinical trials. So from that standpoint it's an unusual situation. It's not a brand new drug, it's a drug where we know a lot about toxicity and a lot about how to use it, but still we have to do the proper trials in order to have it accepted by the FDA as an anti-HIV drug. It's difficult to draw analogies with

T20, for example, which has been developed from scratch. I think we are somewhat in between. We still need a good Phase 2 study and a Phase 3 study before we can ever think about approving the drug for HIV use.

P4P: In terms of things that you are finding most striking or most newsworthy coming out of this conference... Is there anything in particular that is most striking or interesting for you?

Dr. Lori: I think that in the last 2 or 3 years we are more in the mode of conferences that are setting small steps ahead rather than really striking ones. And it's healthy for the field, but not so healthy for the patients that are waiting so anxiously for news. I don't think we can really say that there is anything that strikes as absolutely outstanding in the news. But I think that we are understanding a lot more about the drugs and how to use them. I think we're understanding a lot more about the immune system, which is really what interests us, and I think that we're understanding better how to modulate the immune system in order to have it as the best ally instead of the worst enemy of anti-HIV treatment. We're interested in following the field of therapeutic immunization, because we are convinced that the immune system has something to say and to do way beyond the primary infection. The immune system is active and can be exploited for good cause, I would say almost until the very end, if not the very end. When the immune system is still there it can still be helpful to us, and if you can find a vaccine that would prevent infection, because the vaccine is really for prevention, that could push toward that direction, I think it would serve the cause and many people are moving towards that goal, and quite successfully.

P4P: Last year Dr. Judy Lieberman presented some work on RNA interference, and talking to other folks at this conference so far this year, they are saying that this is a great scientific tool for them in their work. Are you finding uses for or the concept of RNAi helpful in your work at all?

Dr. Lori: We don't use RNAi. I've been following the field and Judy's work, however, which I think is excellent. I think that there are issues on the delivery. I've been involved in the use of oligonucleotides, anti-sense back at the beginning of the 90's, so I'm familiar with the problems, and one of the issues in using DNA or RNA or genes or genetic constructs, is really the delivery. That's what created such a big problem for gene therapy, after all. So what we thought would be very useful, and that's the very concept of the therapeutic immunization that we are proposing, is to use DNA. And instead of trying to find out how to deliver it 100 percent to infected cells, delivery of even 10 percent or 5 percent to immune-competent cells - because immune-competent cells, their job is going to be to expand the information to create a cascade of immune reaction to an antigen that is present even in a minority of cells, because that's the nature of the immune system. So what is a disadvantage in the oligonucleotides, in the gene therapy, in the RNAi field, can become of very important value for therapeutic immunization. Take those genes, deliver them to the immune-competent cells, especially antigen-presenting cells, for example the dendritic cells, Langerhans cells on the surface of the skin, target those.

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It doesn't matter if you don't achieve 100 percent efficiency. You don't even want to achieve 100 percent efficiency, just a small efficiency would be enough to trigger a strong and robust immune response. I think that's a reasonable analogy for what Judy and other people are doing, and what we are doing. We are still focusing on DNA and genetic progress.

P4P: Doctor Lori, thank you so much for your time here today. It's always a pleasure.

1 HU: Hydroxyurea

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Interview with
Charles Rice, Ph.D.
Center for the Study of Hepatitis C
Rockefeller University, New York City

P4P: We are here this morning with Dr. Charles Rice from Rockefeller University, and Dr. Rice has been doing some very interesting work in HCV and co-infection issues. Doctor, I went to your presentation this morning. Could you explain some of the exciting events that have happened in the last year here that have got you up there on the plenary this morning?

Dr. Rice: Well, certainly they are not all events that occurred in my lab, but I think this is a blossoming field. I think that there are a number of things that have been going on, not just basic studies to find out more about how Hepatitis C virus replicates, but I think for the field in general 2003 was an exciting year because we saw some of the first HCV-specific antiviral drugs actually move into Hepatitis C-infected patients in clinical trials. Certainly one of the most exciting pieces of work was from Boehringer Ingelheim in their protease inhibitor that they reported in Nature last fall where two-day administration of this very potent viral protease inhibitor lead to 2 to 3 log drop in the viral load of these people. So I think it's exciting to see basic science actually yield something that works in vivo.¹ Now it's still a very early phase in terms of therapeutic development, and in fact that compound has run into some toxicity issues, but I think it at least tells us that it's possible, and we can hope that there are going to be good compounds in the pipeline. So that's one of the areas.

P4P: In terms of your research and being able to determine more, being able to now culture some of these Hepatitis C cells outside of the body, which I understand has been a big problem, can you explain some of the development that's been going on with that?

Dr. Rice: Yes. One of the things we've been struggling with, with Hepatitis C, is the inability to replicate the virus in the laboratory. This has been a long road that has taken more than 10 years, and we're still not there yet. But I think some advances have been made in terms of being able to mimic the intracellular events and amplification of the viral nucleic acid of the viral RNA that Hepatitis C virus uses. This is called the replicon system. Basically, replicons are self-amplifying and replicating RNAs that will do their thing in cells that are permissive for replication. In the last several years it's been possible to do that in certain human hepatoma cell lines. Most of the machinery that people that are focusing their attention on for antiviral development or for basic studies is encoded in these subgenomic replicons, so the protease, polymerase,

conserved RNA elements that are important for selective amplification of viral genome are all represented in this replication system. It's been a very important breakthrough both for basic studies and for drug development. There are a continuing number of improvements to this system. I guess one of the things that we've learned, though, is that coaxing these RNAs to replicate in cells - and this has been the work of a number of groups around the world - has not yet yielded a complete infectious cycle for the virus. There still seems to be some block in cell culture at the level of assembly or release of infectious particles. So some of the elegant work that's been done with HIV looking at, as you heard yesterday, TSG101 involvement in budding of HIV, we haven't been able to study those processes for HCV. So the quest still continues to get a complete and robust replication cycle in cell culture.

P4P: Do you see possibilities here with developments in this last year with research tools, such as the RNAi, where do you see research going in terms of development in the coming years in terms of being able to reproduce in the lab an entire life cycle for HCV?

Dr. Rice: I think one of the exciting aspects in molecular virology and in mammalian cell biology has been the recognition that RNA interference actually isn't just working in plants and nematodes and flies, but is also works in mammalian cells. That gives us a tool that allows us to explore cellular factors that may be important for virus replication

in a way that we couldn't do before. As a research tool, RNAi (RNA interference) is proving to be extremely useful for Hepatitis C, HIV, and for other research efforts. The other exciting thing about RNAi is that it does have the potential of being a therapeutic, I guess as you heard last year from work from the Lieberman lab. We don't know how it's going to work as an antiviral, but certainly the proof of concept experiments in cell culture have been done. You can eradicate functional HCV RNA from this in vitro cell culture replicon system. How difficult it's going to be to deliver si-RNAs or the RNA interference signal to target HCV RNA to every infected cell or potentially every infectable cell in a person, is another matter. That's probably going to keep the companies that are working on this technology busy for some time, but I think it's an exciting possibility because, the platform is so general that if it works you can apply it to a number of different viral RNA sequence targets, you can target very highly conserved portions of the viral genome that would be



difficult for the virus to escape from, so a very, very exciting new technology.

P4P: Do you see that moving into primate models anytime soon?

Dr. Rice: People have certainly been talking about that. I guess what we've seen so far have been the cell culture and smaller animal model experiments. The challenge always in moving into primate models is the amount of material that you need to achieve the same dosing. But I think people will give it a try in primate models fairly soon. That may be led by the SHIV models, for retrovirus control rather than Hepatitis C in chimpanzees. We have two potential kinds of animal models that we can use for Hepatitis C. One is the chimpanzee, which as you know these animals are limited and expensive, so it's difficult to do experiments that involve large numbers of animals. And there are some chimeric² mouse models, where they have human liver that is engrafted into an immunodeficient mouse rendering them susceptible to Hepatitis C virus infections. It may be that, at least in terms of HCV in vivo, those would be the first kinds of models that will be tested.

P4P: That would be kind of like perhaps stemming off of Dr. Lieberman's work last year with her mouse models?

Dr. Rice: Right. But I think one of things that's going to have to be done is to figure a less invasive way of getting good delivery of the si-RNAs³ to cells, rather than hydrodynamic injection.

P4P: On developing a vaccine... it's going to be very difficult, in the same fashion that it's going to be very difficult for HIV-vaccine development, because there are so many variants of HCV. Where do you see progress at this point? Would you be willing to go out on a limb and say there might be a possibility of a therapeutic vaccine that may be efficacious to X-percent in X-time?

Dr. Rice: I probably wouldn't want to go out on that limb, because I know it's been sawed off before. (Laughter.) I think that vaccination for Hepatitis C, even prophylactic vaccination, is going to be challenging just because of the immense variability that exists and the cleverness of this virus in avoiding the immune response. That said, I think conceptually for Hepatitis C, I think development of vaccine is going to be much easier than it is for HIV. First of all, it is an RNA-only life cycle, it doesn't integrate, and we have examples of people that have spontaneously cleared the virus, and we also have examples where people really show a sustained virologic response to treatment - as far as we can tell, elimination of the virus after it was there. So that means that this virus can be eliminated under the right circumstances. That's a big difference between HIV and HCV. Another thing is that the vaccine for Hepatitis C doesn't have to provide sterilizing immunity, doesn't have to prevent infection, as long as it prevents the progression to chronic infection. So again, even if you didn't have a perfect vaccine, so that you go no infection at all, if you had a vaccine that gave the immune system a head start, gave it the help it needed to clear the virus in most cases, that will be sufficient for HCV. So conceptually it's easier. Practically, I think

we're still a little ways away. I wouldn't want to predict how long it will take to develop the vaccine because there are still a lot of basic principles about how this virus interacts with the immune system that we do not understand at all. And that's true for a prophylactic vaccine. When you're talking about a therapeutic vaccine, there really aren't too many examples of successful therapeutic vaccines but, this is a very important goal in Hepatitis C with 150 million or so people that are chronically infected and not all of them are probably going to be in a situation where they can afford the best antiviral therapy as it comes along. Having a therapeutic vaccine would be of tremendous importance, and in fact we don't really even know what the defects are in chronic infection with Hepatitis C, because it doesn't cause a generalized immunodeficiency. It seems to be something which is more specific to the regulation of HCV itself, and so it's probably going to be important to even think about boosting the immune response in the context of antiviral therapy in order to achieve eradication, because people who are chronically infected somehow can't eliminate the virus. Even if you have a perfect combination of polymerase inhibitor and a protease inhibitor where you could stop replication and have no possibility of drug resistant variants emerging, there's still the issue of whether or not the immune system is present in a chronically infected individual to mop up what's left and get rid of the virus. So, this is an area of very active research in Hepatitis C. It's a very complicated and exciting area. I'm cautiously optimistic about vaccine development for Hepatitis C.

P4P: One thing I know a lot of folks are not aware of... I saw in your presentation this morning that you estimate 2 percent of the world's population are infected, which is close to 200 million people... I don't think many people realize the extent of this other pandemic. Being that it takes so long for someone to progress to 3rd Stage where you're developing CA in the liver, etc., what's the prognosis here, vis- -vis the AIDS pandemic?

Dr. Rice: I think that you've hit the nail on the head in a sense. Even though there are more people that are infected with Hepatitis C, the predictability of disease progression has been a frustration for both the clinicians and their patients. We don't know why some people progress to cirrhosis and liver failure and other people may have some inflammation in the liver and trace amounts of scarring, but they're fine. They lead an otherwise healthy and normal life. So I think that's one reason why the epidemic has not achieved the dramatic public recognition that it perhaps deserves. That's the reality of it. I think in terms of... for those of us working in the field the fact that it is a slow progressive disease means that people have a little bit more time in some cases to decide what kind of treatment options they're going to choose, and these are continuing, improving, and evolving as science and clinical research marches forward. People are becoming aware of it, but you're right; there are a number of misconceptions... if you say viral hepatitis, most people think more about Hepatitis A, a food-borne fecal-oral transmission route, rather than Hepatitis C, because that's a dramatic acute usually

resolving infection, whereas Hepatitis C is silent but potentially deadly in the long term.

P4P: In terms of clearing the virus, are there particular clades⁴ that are more easily cleared by the host compared to other clades of the virus?

Dr. Rice: In terms of natural infections with Hepatitis C, in terms of looking at the frequency of acute resolvers versus chronics, there's not a big difference between the different HCV - we call them genotypes⁵ and subtypes within a genotype, there are six of these. So, in terms of the ability of the immune system to control the virus, not a big difference. Now, in terms of the outcome of treatment, there is a big difference, and that's really right now the only biological difference that we have between these different HCV genotypes. Genotype-1, which is the most common genotype in the U.S., Europe and Japan, is unfortunately the most difficult one to treat. With the current therapy, which is pegylated interferon and ribavirin, for genotype-1 only about half of those treated are able to eliminate the virus. That's defined as absence of detectable HCV RNA at the end of treatment and then also 6 months later. Genotypes-2 and -3 are much more easily treated, and the current treatment for those is probably 85-90% successful.

P4P: Doctor Rice, I want to thank you so much for your time here this morning. It's been a pleasure and an enlightenment for me, because I'm kind of rusty on the HCV stuff, so I really appreciate it. On behalf of the folks that can't be here, I'd like to say thank you for them also.

Dr. Rice: Thank you very much for having me. It's been a pleasure.

1 In vivo: In the living organism, as opposed to in vitro (in the laboratory).

2 Chimeric model: An organism that contains cells or tissues with a different genotype. These can be mutated cells of the host organism or cells from a different organism or species. From the Greek chimera.

3 siRNA: Small interfering RNA, or siRNA, is a short RNA duplex between 15 to 21 nucleotides in length. These duplexes have two-nucleotide overhangs on their 3-prime ends and are phosphorylated on their 5-prime ends. Once transfected into cells, siRNA, in conjunction with cellular machinery, targets messenger RNA molecules containing an identical sequence for degradation in a catalytic manner. The degraded message is no longer functional in translation (the biosynthesis of protein) and thus in the expression of the corresponding gene. Designer siRNA molecules targeting a gene of interest can be transfected into cells to suppress the expression of that gene.

4 Clade: Related organisms descended from a common ancestor. For example, isolate M of HIV-1 (the human immunodeficiency virus) consists of at least ten clades. Imported from the Greek, klados, branch in 1911 in reference to the Tree of Life.

5 Genotype: The genetic make-up of an individual organism.

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Interview with
Joep M.A. Lange, M.D., Ph.D.
University of Amsterdam, Academic Medical Center
Amsterdam, The Netherlands

P4P: We're here at the 11th Conference on Retroviruses and Opportunistic Infections in San Francisco, California, with Joep Lange who works at the University of Amsterdam, Academic Medical Center, The Netherlands. Doctor Lange, thank you very much for making an appearance here with us, so early in the morning. We really appreciate it. I know you've been doing a lot of international work, some work with former President Clinton and PharmAccess International Foundation that you chair. I'd like to ask you to explain some of what that work with PharmAccess involves and how the work is going.

Dr. Lange: PharmAccess came into existence in 2000 when the drug prices came down for antiretrovirals, and what PharmAccess wanted to do was speed up the process of getting people on antiretrovirals in Africa. It was our opinion that, a lot of the governments wouldn't be moving very fast, because the public sector in a lot of African countries is very weak, so we thought you have to start in places where they can do the job. What we did, we went to companies that we know have a presence in Africa, some multinational companies and national companies in different countries, and tried to convince them to start providing antiretrovirals to their personnel, and hopefully also to their dependents. Our first customer was Heineken - they have breweries in 9 African countries, and they committed to start to provide therapy to their employees and their dependents, actually lifelong therapy. What PharmAccess does is, first of all, try to convince them (companies) that they should be doing this, and then secondly we provide the technical advice for them to be able to do it. What we're now... this was the first step, because we thought you have to go there where they can do it. What we're now trying to do is link private sector programs with public sector programs, and also get the communities around the companies involved. It's not been easy. The public sector has been very, let's say reluctant to take this on. Obviously it would be great if the companies could provide the infrastructure. Because they have the infrastructure, they can provide a lot of things, where the public sector could then come in and get things for a relatively low price. We now got a large grant from a Dutch national for a lottery for Namibia, and in Namibia I think we will be able to really link public and private sector programs. Apart from that we have been engaged by the Clinton Foundation to be one of their partners in the work that they do, especially in South Africa and in Tanzania, and that's not private sector,



that's really a public sector approach.

P4P: On the lighter side, when you mention Heineken, does that mean that we can look forward to any medications that we can take with Heineken?

Dr. Lange: (Laughter). I must say that I usually drink Heineken now because they're doing such good work. They have been exceptional. They have also done a lot of advocacy with other companies trying to convince them to start doing this. They're one of the few companies that provide therapy to dependents. Most companies only provide therapy to the employees. And they have commitment for life-long therapy, even if people leave the company.

P4P: That's really excellent. In terms of IATEC... The International...

Dr. Lange: International Antiviral Therapy Evaluation Center.

P4P: Right. I know that's been in operation for quite some time. What are you doing with IATEC?

Dr. Lange: IATEC is a clinical research organization that tries to do independent clinical research on issues that we think are relevant. We have no real public funding, so we need to get money from customers, and that may be Pharma, it may also be UNAIDS or other foundations. We really try to do studies that we think are necessary. For instance, the 2NN, the study we did comparing

nevirapine and efavirenz. We're doing a lot on prevention of mother-to-child transmission in Africa. So IATEC tries to come up with ideas and then secure the financing to put those ideas into action in clinical trials. Obviously you often have to compromise. We may have a very good idea about a strategic trial but you always have to adapt to funding possibilities.

P4P: Is there any connection with IATEC in terms of the Clinton Foundation? Are you going to be able to get any support from the Clinton Foundation for any of this?

Dr. Lange: No, PharmAccess is working with (the Clinton Foundation). So PharmAccess and IATEC, although they have the same roots, they are so different. One is really (focused) on scaling up access to care and the other is on research. I think there's a lot of potential for synergy, but the types of people who work in the two places are very different. It was actually better to separate them to a certain extent.

P4P: I know there's been a lot of work going on for Bangkok, for the upcoming World AIDS Conference there in July. How has that work been progressing in terms of organizing that conference? What kinds of good news is there, and what kinds of bad news is there?

Dr. Lange: I think the concept of the conference is very interesting, because it's different from every AIDS conference that was there before. I think it's increasingly acknowledged that leadership is extremely important, engaging political leaders in the fight against HIV/AIDS. In those countries where the political leaders have stepped up and been upfront about HIV/AIDS have actually made a difference. There's still a lot of countries where the political leaders are not doing that. For Bangkok, we really want to pull in the leaders to come to the conference and make sure that they understand the importance of doing something about HIV/AIDS....

P4P: Light a little fire underneath some of them.

Dr. Lange: Yes, in a constructive way, because if we just throw tomatoes at them or criticize them they're not going to do anything. What we really want to do is to try to bring together those that have performed and those that haven't. Obviously you can't bring all the leaders of the world. First of all they wouldn't come. Second, the security concerns become enormous. In Bangkok what we now have, apart from the scientific program and the community program, we also have a leadership program. Getting political leaders, also getting leaders from the business sector, getting leaders from the community, getting leaders from different religious affiliations, and try to bring them together and have special sessions devoted to leadership. We'll have a number of plenaries on leadership. We will also have meet the leader sessions where people can question the leaders. We're going to have symposia, where they can be interviewed. For instance, a number of people have already said they would be coming, your President Clinton will be coming, Kofi Annan will be coming, Mr. Wolfensohn, president of the World Bank will be coming, a number of national leaders are going to come to Bangkok. So from that perspective, I think the conference is going to be very interesting.

I think the bad news about the conference is that, of course, all of the promises that the big multilaterals have been making about how many people would be on therapy by now, I think it's going to become clear at the conference if they're honest, that the 3 By 5 Framework¹ is not going to be met. And I think we have to be quite critical about that. It is an opportunity to not let them off the hook, and come up with an explanation of why we have this blah-blah, and why we're not going to reach that target.

P4P: And where we need to go to get there.

Dr. Lange: Yes. Because I think that's the big problem is that, there's always blah-blah, but we need to do this, we need to do that, but still a decent action plan is still missing. And we've tried very hard to get this international collaboration going. We founded the International Treatment Access Coalition at a certain stage to really try to bring the players together. That has been replaced by 3 By 5, but I'm actually not impressed by the pace of progress that 3 By 5 is making. I think it's going to be a conference of accountability.

P4P: I'm really excited to hear about the leadership segment at this conference.

Dr. Lange: Yes, but it's only going to be successful if we can really also be engaged in critical dialogue and not just have blah-blah, we're doing this, we're doing that.

P4P: I think that would be very influential, if President Clinton and his foundation and other international leaders, like Kofi Annan...

Dr. Lange: Nelson Mandela will come. President Machel, his wife is actually one of the patrons of the conference.

P4P: Once folks see who's there they have more of a tendency to perhaps want to jump on board.

Dr. Lange: Yes, that's the whole idea. And we'll have people from the media, from the entertainment sector. We've got a number of big actors from the U.S. that will be coming.

P4P: You're gearing up to do some vaccine work.

Dr. Lange: Yes, therapeutic vaccine work.

P4P: Therapeutic, which is good. Can you give me any information on where you're at in that process?

Dr. Lange: Yes, that has been an exceedingly slow process. This is a European Community grant that we have together with Brigitte Autran from Paris and Jeffrey Cantelejo from Rosano. It's a European-made vaccine funded by the European community. One of the problems has been, the first company was going to produce the vaccine and suddenly decided they were not going to produce it, so just getting the vaccine produced has taken an enormous amount of time. I've learned that the vaccine world is very different from the therapeutic world. It's not like you can start a trial overnight. It actually takes quite a while before you get somebody to produce the vaccine to support a trial like that.

P4P: The vaccine construct, it is designed for HIV-1 or the virus that may be particular, say, to Southeast Asia?

Dr. Lange: No, this is a B-subtype, so this is the virus that is the dominant virus in the U.S., and I was going to say in Europe, but that's changing rapidly, because of all the immigrants. Most of our new patients have non-B virus. There is another similar construct, which is actually made by EuroVac, that is a non-B virus, that is a C-subtype virus. The one that we're using as a therapeutic agent is a B-virus, and the idea of this study to see whether we can postpone the initiation of treatment or delay - if you interrupt treatment - the restart of treatment...

P4P: Or increase the length of interruption.

Dr. Lange: Exactly, yes. There's another field that we've become interested in, and that's microbicides. We're getting heavily involved in microbicides research in Africa.

P4P: Are there any particular compounds that you're working with? I know they're doing some stuff with...Gilead is doing some stuff with viread, where they're trying to develop gels and other things.

Dr. Lange: Yes, and Gilead is also doing this big study funded by (The Gates Foundation) with viread as an oral prophylactic, which I think is going to have the best chance of working.

P4P: Do you think viread as a preventive prophylaxis is really going work?

Dr. Lange: I think it's going to work.

P4P: You do?

Dr. Lange: I'm very...

P4P: You're very optimistic?

Dr. Lange: And it's not just viread. Other drugs would also work. In fact, we did this study called SIMBA, which was presented in Paris last year, a study to prevent transmission from breast-feeding mothers to their infants, and for the duration of breast-feeding we gave the infants a single pill of either niverapine or 3TC per day, and that actually worked. It was very effective in preventing transmission. So I don't see why an adult taking a pill prophylactically shouldn't be protected from sexual transmission.

P4P: That's really exciting.

Dr. Lange: Yes, it's extremely exciting, also because a vaccine is going to take...before we have an effective preventive vaccine, if we're optimistic it's going to be 10 years...

P4P: It's already been 10 years.

Dr. Lange: Yes, it's always ten years. First it was 2 years, then it became 10 years. It's always 10 years.

P4P: Doctor Lange, I know you're racing to get to another appointment this morning. Thank you so much for taking the time to sit with us this morning and answer a few questions. I know that those who are not privileged enough to be here at this conference will be very grateful to you.

Dr. Lange: Thank you, Jeff, and I hope to see you in Bangkok.

1 3 by 5 Framework: The WHO and UNAIDS global initiative to provide antiretroviral therapy to 3 million people with HIV/AIDS in developing countries by the end of 2005.

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Interview with
Lillian Mworeko
National Forum for PLWHA in Uganda
Kampala, Uganda

P4P: Our guest interview is with Lillian Moreko from Uganda, and Lillian is going to be talking to us about the National Forum of People Living With HIV/AIDS Networks in Uganda. This is a new group that has been formed as an umbrella group for existing PLWHA networks in Uganda. Lillian, please tell us all about it. How did the organization get started? What is your position, what are you doing within the organization? What does the organization seek to do?

Ms. Mworeko: Thank you. This is a forum of people living with HIV and AIDS in Uganda. It brings together all associations and groups of people living with HIV and AIDS, and our main purpose is to ensure that we have a common voice to fight for our rights, and to ensure that all people living with HIV and AIDS at all levels have been heard and are well represented. It was formed in May 2003 after realization that there was nobody, no organization that was bringing together all associations and networks in the country. I work as the Capacity Building Officer in the organization.

P4P: Have you instituted any programs or services with this new organization? Can you describe some of the activities that you are involved in?

Ms. Mworeko: We have yet to carry out a strategic plan that will guide us on what we do as a forum, but before that we will carry out a needs assessment, which will be done shortly. We hope to be guided by the needs assessment, which is going to form the strategic plan, and thereafter we will forge ahead with what we need to do as the forum.

P4P: What sort of capacity building activities will you be doing in your position as Capacity Building Officer?

Ms. Mworeko: I see myself bringing together all people living with HIV and AIDS with some expertise, trying to enhance their skills and capacity so that they can respond greatly to the pandemic. Many times as people living with HIV and AIDS, we have been used, not greatly, but we realize we have some skills that can be enhanced, and through that we can really participate greatly in the fight against HIV and AIDS. We really need to enhance the skills of the people so that we can scale up our response in the fight against HIV and AIDS.

P4P: Will you be working with other groups, like TASO, in trying to help expand ARV access or education of individuals prior to receiving ARV, so that they know what to expect? Will you be working with other groups, like the AIDS Service Organization in Uganda?

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Ms. Mworeko: We will be working in partnerships and collaborations, and we will look at where our cooperative advantage is. In our country we have what we call the National HIV/AIDS Partnership, which brings together all key players in the fight against HIV and AIDS. As we sit in our meetings we try to see which group is best at doing what, and that's where we come in. We are going to really work as a team, bringing together everyone on board, but especially coming up with what we feel as people living with HIV/AIDS what we can bring on board in order to enhance our participation.

P4P: Is this your first trip to the United States?

Ms. Mworeko: Yes, this is my first trip here.

P4P: What sorts of sessions were you finding most interesting at the conference?

Ms. Mworeko: I was more interested in sessions that dealt with antiretroviral drugs and microbicides. But I should also mention that I was really touched.

In almost all the sessions I realized that despite the fact that sub-Saharan Africa is most hit by the pandemic, I didn't see much of our participation in this. Therefore, it is something that we are going to take up with my colleagues from the African continent to ensure that in subsequent conferences we have more representation.

P4P: In terms of microbicides, what did you find most encouraging? Do you know if there will be

any microbicides trials in Uganda?

Ms. Mworeko: I didn't hear that, but what I did hear was the fact that there's a need to mobilize people who are going to use these microbicides, and I realize that that's where we come in as people living with HIV/AIDS. We know people who need these microbicides, we know where they are, and they very much listen to us. Therefore, our role is going to be in mobilization; giving out information as to where, how these microbicides are going to be used, when they'll be available and the advantage of using them.

P4P: As you return to Uganda, what message would you like to leave people living with HIV/AIDS and AIDS activists in the U.S.?

Ms. Mworeko: In sub-Saharan Africa, people are dying day by night, and it is unfortunate that people are dying when there are antiretroviral drugs available. I call upon everybody to respond so that history does not judge us. It's really unfortunate to see people die when their lives can be saved.

P4P: Thank you very much, Lillian.

Ms. Mworeko: Thank you.



Wyoming: Positives For Positives 2003 Year End Report and Financial Statement

By Jeff Palmer

In 2003 the combined support of Wyoming: Positives For Positives's (WPPF) benefactors was valued at \$116,424.13. Direct financial support totaled \$54,201.02. Income donations for condoms amounted to \$80.00, local businesses contributed \$340.00, while grant revenue and sponsorships totaled \$48,321.74 and came from nine (9) different supporters. (See box next page).

Donations from individuals totaled \$2,556.00; Bulk mailing services to other businesses generated \$1,236.98; contractual agreement with Wyoming Department of Health for HIV Counseling & Testing services provided \$420 of income; combined sales from our web-store and retail storefront in Cheyenne offered \$1,170 revenue; and finally speaking honoraria and interest income amounted to \$76.30.

In-kind contributions were valued at \$62,223.11. Contributions of medications sent to Uganda were valued at \$22,606.32 AWP (US average wholesale pricing). Volunteers donated 3,333 hours of time valued at \$23,334. Scholarships and sponsorships to meetings and conferences totaled \$11,923. Donated professional services amounted to \$2,075 and donated office supplies and equipment were valued \$935.29. Condoms donated were valued at \$1,150 and complimentary emergency housing was valued at \$200.

Total Expenses in 2003 amounted to \$52,588.21. The agency addresses its mission in three distinct program areas: Client, Information/Education and International services. Expenses for these program services amounted to \$29,929.12 or 57% of total expenditures. Operating expenses totaled \$22,659.09 or 43% of total expenses.

WPPF relocated again in 2003. From the new location the agency has continued to provide services locally, nationally and internationally. For **Client Services** in 2003, \$593.66 was spent for attendance at conferences and supplemented in-kind scholarships and sponsorship. Additionally, \$739.22 was spent on emergency financial assistance to two (2) clients, \$272.40 for laundry service serving three (3) clients, \$2,768.58 was spent for lunches and meals serving ten (10) clients, \$287.40 was spent on multi-vitamins serving nine (9) clients, and transportation services were provided to four (4) clients. Total Client Service expenditures amounted to \$4,661.26 and an additional \$3,463.14 provided stipends to seven (7) infected individuals for their work in writing, publication and distribution WPPF's quarterly newsletter and other mailings.

During 2003, the agency continued offering bulk mailing services to other businesses and continued operating our commercial storefront and Webstore (www.pos4pos.org). WPPF anticipates that income generated from these activities will continue to grow with time offering more and more support for both infected individuals and the agency.

Bulk Mailing Service operated for a net loss of -\$81.92. This loss occurred due to acquisition of new mailing equipment and software from Pitney Bowes. For future mailings the new equipment will enable the office to realize a savings of \$2,800 annually in postage, printing and mailing services for agency mailings. Furthermore it will offer WPPF additional opportunity to generate operating income by offering mailing services to other businesses.

Gross sales from the storefront and Webstore amounted to \$1,170 and generated \$620 net income. Sales of donated items accounted for \$745 of gross, while sales from arts and crafts by infected individuals was \$425 of gross sales.

Expenditures in support of these activities totaled \$550. Of this amount, \$462 was used to purchase additional arts and crafts from infected individuals and \$88 was spent on miscellaneous store fixtures.

The generous support received in 2003 also enabled WPPF to offer **Information/Education** services through the distribution of 11,376 male condoms, 1,314 female condoms, 443 dental dams, 644 packets of lubricant, 1,336 educational brochures on how to use a condom and HIV counseling and testing sites in Cheyenne. The agency provided seven individuals with HIV counseling and testing during the year.

Safer sex items and testing information were distributed at special events, exhibits, our office and through five (5) other local businesses which allow the agency to maintain condom displays in their establishments throughout the year.

WPPF participated at 5 different local exhibits and speaking engagements reaching more than 150 people in Wyoming with current and accurate information on HIV/AIDS. The agency collaborated to sponsor two lectures on the clinical care and treatment of HIV disease to area physicians, pharmacists, nurses, case managers and HIV infected individuals. These two events are sponsored by pharmaceutical representatives, WPPF and the University of Wyoming Family Practice Residency Program in Cheyenne and offered updates to 45 local care providers. Exhibits combined with presentations through our Lectures and Speakers program reached nearly 200 individuals locally.



The agency library provides comprehensive and current information on HIV research, treatment, prevention, political advocacy, non-profit development, and PWA self-empowerment. In 2003, the library had 63 visits from local clients, volunteers and care providers. Another 30 requests were received via email, six (6) from individuals nationally and 24 requests from groups or individuals in developing countries.

The agency website (www.pos4pos.org) was redesigned and updated in 2003. At the website viewers can view information about the agency, the mission, the programs and services. *Positives For Positives*, the agency's quarterly newsletter can be viewed or downloaded and a new Advocacy page was launched during the last year. The agency E-store continues to attract supporters and contributors can now make on-line donations. The most frequently visited pages are for newsletters or E-store items and currently the site averages 55 hits per day.

Through the agency's newsletter services, WFPF distributed 45,298 publications to more than 17,000 readers worldwide. Distribution of *Positives For Positives* totaled 42,612. Also in 2003 the agency redistributed to readers locally in Wyoming 671 *Body Positive*, from Body Positive, New York City; 672 *Positively Aware*; TPAN (Test Positive Aware Network), Chicago; 70 *BETA* (Bulletin of Experimental Treatments for AIDS), San Francisco AIDS Foundation, San Francisco; 259 *HIV Plus* from Liberation Publications, Los Angeles; and 1,172 *POZ* from Smart & Strong, LLC, New York City. Additionally, 38 texts, *AIDS Update 2003*, were distributed to HIV infected activists in Poland, the United States and Uganda. Another 62 texts are still to be distributed to activists in Argentina, Cameroon, Kenya, Mexico, Nigeria, Tanzania and Trinidad.

Attending conferences and meetings is a key aspect in assuring the agency's ability to offer quality community media coverage of these events and the latest scientific and research developments. In 2003, the director attended a total of 10 separate meetings during the year. Without the support of scholarships and sponsorships, attendance at these meetings would not have been possible. Three of these meetings were covered in *Positives For Positives*, the 10th Conference on Retroviruses and Opportunistic Infections, Boston, MA, USA; the 2nd IAS Conference on HIV Pathogenesis and Treatment, Paris, France and the 11th International Conference for People Living with HIV/AIDS, Kampala, Uganda. Although not reported in the quarterly newsletter the annual HIV Summit sponsored by GlaxoSmithKline also was attended. Three meetings related to Community Prevention Planning, the Community Planning Leadership Conference, New York City and two local community planning meetings in Wyoming.

Because advocacy remains a critical component of the agency, WFPF continued advocacy efforts for affected populations and continued to maintain ties with other national and international groups. To this end, the agency continues to weigh-in with elected officials, pharmaceutical companies and other infected/affected activists around the

world on issues of prevention, care, research, housing, human rights, global concerns and appropriations.

The director attended two meetings with ATAC (AIDS Treatment Activists Coalition) and a third event sponsored by the Global Health Council featuring Senator Mike Enzi of Wyoming as the guest speaker. The ATAC meetings took place in Houston and Chicago. Houston was an organizational meeting of ATAC and Chicago was a meeting with pharmaceutical representatives from companies involved in the development of fusion inhibitors. The third advocacy event took place in Jackson, Wyoming where WFPF was critical of Senator Enzi's voting record of consistently under funding both domestic and international HIV programs. Although Senator Enzi was singled out at this meeting, the voting records of Wyoming's other elected representatives are no different as is the collective voting record of the entire US Congress on these issues. In it's advocacy work the agency promotes full and complete funding for HIV/AIDS programs, while opposing attempts to under fund other disease conditions. Our advocacy is consistent in that respect. The agency advocates always for **new** money and opposes policies that sacrifice appropriations in other health care areas. Total expenditures for all the agency's information/education services amounted to \$24,743.06.

Internationally in-kind support from contributors made it possible to supply \$22,606.32 of anti-viral medications to infected individuals in Kampala, Uganda and to invest \$550 in the arts and crafts of infected individuals and groups from developing countries and here in the U.S. WFPF remarkets these items via auctions, the agency's E-store and our retail store here in Cheyenne. A portion of the profits from these efforts help cover infrastructure costs for WFPF with another portion is used to expand the program and purchase other crafts and products from individuals and groups infected/affected by HIV.

The trust, support and contributions of all our supporters made all these activities possible and enabled WFPF to combat HIV on many fronts. Their kind and generous support is most appreciated. It has saved lives and made a difference for many others. As importantly, it inspires further philanthropic giving by others.

Questions or requests for more information about agency programs, planned future activities or opportunities to contribute are encouraged. A copy of WFPF's IRS form 990 also will be available on-line later in 2004.

Abbott Fund	\$ 1,500.00
Abbott Laboratories	2,500.00
Boehringer-Ingelheim	2,000.00
Bristol-Myers Squibb	7,500.00
Broadway Cares/Equity Fights AIDS	10,000.00
Gilead Sciences	5,000.00
GlaxoSmithKline	2,500.00
Opler Foundation	10,000.00
Wyoming Department of Public Health	<u>6,071.74</u>
Total Grants and Sponsorships	\$47,071.74

Positives For Positives 2003 Year End Financial Statement

Donations and Income

Category	Budget	% of Total Income
Business (Local)	\$340.00	0.63%
Condoms	\$80.00	0.15%
Grants	\$39,571.74	73.01%
Individuals	\$2,556.00	4.72%
Sponsorships	\$8,750.00	16.14%
Bulk Mailing Services	\$1,236.98	2.28%
HIV Counseling & Testing	\$420.00	0.77%
Store	\$1,170.00	2.16%
Speaking	\$75.00	0.14%
Interest	<u>\$1.30</u>	<u>0.00%</u>
Total Income	\$54,201.02	100.00%

Expenses

Client Services

Category	Budget	% of Total Expenses
Conference	\$593.66	1.13%
Emergency Financial	\$739.22	1.41%
Laundry	\$272.40	0.52%
Meals	\$2,768.58	5.26%
Supplements	<u>\$287.40</u>	<u>0.55%</u>
Total Client Services	\$4,661.26	8.86%

Information/Education Services

Category	Budget	% of Total Expenses
Condoms	\$3,475.00	6.61%
Library	\$1,392.70	2.65%
Newsletters	\$19,755.44	37.57%
Public Advocacy	<u>\$119.92</u>	<u>0.23%</u>
	\$24,743.06	47.05%

International Projects

Category	Budget	% of Total Expenses
Uganda Medications	\$62.80	0.12%
Arts & Crafts	<u>\$462.00</u>	<u>0.88%</u>
Total International	\$524.80	1.00%

Operating Expenses

Category	Budget	% of Total Expenses
Bulk Mailing	\$1,318.90	2.51%
Executive Director	\$1,050.43	2.00%
Equipment/Furnishings	\$439.55	0.84%
Equipment Rental	\$710.00	1.35%
Office Expenses	\$3,013.38	5.73%
Rent, Utilities & Phone	\$11,682.60	22.22%
Store	\$88.00	0.17%
Supplies	\$2,859.69	5.44%
Taxes & Licenses	\$205.00	0.39%
Van Operating Expenses	\$1,216.37	2.31%
Volunteer Expenses	<u>\$75.17</u>	<u>0.14%</u>
Total Operating Expenses	\$22,659.09	43.09%
Total Expenses	\$52,588.21	100.00%

**On Behalf of All Those We Serve,
Positives For Positives Wishes to Thank Our Supporters in 2003.
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